

1. NOW COME Plaintiffs Jennifer Lane, DVM, and Rebecca Blackwood, DVM and complain of Defendants Scott & White Healthcare; Scott & White Memorial Hospital and Scott, Sherwood and Brindely Foundation d/b/a Scott & White Healthcare; Scott & White Clinic; and Richard Beswick, PhD, MBA.

I. PARTIES

2. Plaintiff Jennifer Lane, DVM, is a natural person and a resident of Middlesex County, Massachusetts.

3. Plaintiff Rebecca Blackwood, DVM, is a natural person and a resident of Bell County, Texas.

4. Defendant Scott & White Healthcare is a Texas corporation and has already answered and appeared in this proceeding.

5. Defendant Scott & White Memorial Hospital and Scott, Sherwood and Brindely Foundation d/b/a Scott & White Healthcare is a Texas corporation and has already answered and appeared in this proceeding.

6. Defendant Richard Beswick, PhD, MBA is a natural person and has already answered and appeared in this proceeding.

7. Defendant Scott & White Clinic d/b/a Scott & White Memorial Hospital d/b/a Scott & White Healthcare System is a Texas corporation and may be served through its registered agent, Mr. Jimmy L. Carroll, at its registered office, located at 2401 S. 31st Street, Temple, Texas 76508.

II. JURISDICTION AND VENUE

8. Jurisdiction is proper because, in part, this civil action arises under the Constitution and laws of the United States. 28 U.S.C. §§ 1331, 1367(a).

9. Venue is proper because the Defendants reside in the Western District of Texas and a substantial part of the events or omissions giving rise to the claims occurred therein. 32 U.S.C. § 1391(b).

III. FACTS

10. In 2008, Defendants Scott & White Healthcare, Scott & White Clinic, and Scott & White Memorial Hospital and Scott, Sherwood and Brindely Foundation d/b/a Scott & White Healthcare (hereinafter collectively “Scott & White”) engaged Drs. Jennifer Lane and Rebecca Blackwood as veterinarians for the laboratory animal programs of Scott & White, the Texas A&M Health Science Center on the Temple Campus (hereinafter “Texas A&M”), and the Central Texas Veterans Health Care System (hereinafter “Veterans Health Care”).

A. Joint Enterprise

11. For over 30 years, Scott & White, Texas A&M, and Veterans Health Care have operated an accredited medical school, the Texas A&M University College of Medicine.¹ The College uses Scott & White’s Temple Campus and the Olin E. Teague Veterans Center (hereinafter “Temple Research Facilities”) as the core clinical campus and primary teaching facility of the College of Medicine.²

¹ See Affiliation Agreement Between the Texas A&M University System and Scott & White Clinic, Scott and White Memorial Hospital and Scott, Sherwood and Brindely Foundation and the Texas Central Veterans Health Care System (Aug. 24, 2000) (hereinafter “Affiliation Agreement”), a copy of which is attached hereto as Exhibit A; see also Texas A&M Health Science Center, *About the College*, <http://medicine.tamhsc.edu/about/> (last visited June 8, 2012).

² Ex. A, Affiliation Agreement, p. 1.

12. Texas A&M, Scott & White, and Veterans Health Care thus collaborate in a joint effort “to attain excellence in . . . the advancement of medical knowledge through investigation and publication of the results.”³ Specifically, they jointly engage in biomedical and behavioral animal research. In 2000, the parties expressly committed themselves to the goal of a completely integrated research program.⁴ On information and belief, there are numerous joint appointments amongst the three entities.

13. It appears that an essential aspect of the collaboration is the sharing of resources dedicated to compliance with laws and regulations governing research and the avoidance of duplication on this front.⁵ Texas A&M, Veterans Health Care, and Scott & White have “expressly agree[d] to use their respective mechanisms of assurance for the benefit of the mutual programs and where possible to eliminate duplication.”⁶ Additionally, they have agreed to utilize “common peer review mechanisms for scientific review of research protocols” and otherwise share resources.⁷

14. Drs. Lane and Blackwood were engaged in connection with this integrated research program to satisfy the federal requirements of veterinary care for the Temple Research Facilities. They were tasked with developing and implementing a program to ensure compliance with the federal laws and regulations governing the treatment of laboratory animals,⁸ with enforcing compliance, and with reporting violations to appropriate regulatory authorities.

³ Ex. A, Affiliation Agreement, p. 2.

⁴ Ex. A, Affiliation Agreement, pp. 10-11.

⁵ Ex. A, Affiliation Agreement p. 10.

⁶ Ex. A, Affiliation Agreement p. 10.

⁷ Ex. A, Affiliation Agreement p. 10.

⁸ 7 U.S.C. §§ 2131, *et seq.*; 9 C.F.R. §§ 1.1, *et seq.*; 42 U.S.C. § 289d ; Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820, § 495; OFFICE OF LAB. ANIMAL WELFARE, NAT’L INSTS. OF HEALTH, DEPT.

15. According to public filings to the Texas Secretary of State, Scott & White Clinic and Scott & White Memorial Hospital and Scott, Sherwood and Brindely Foundation d/b/a Scott & White Healthcare are wholly-owned subsidiaries of Scott & White Healthcare. These three entities jointly operate the research facilities in conjunction with the Veterans Health Care and Texas A&M. The three-named Scott & White entities are vicariously liable for each other's conduct.

16. Defendant Richard Beswick, PhD, MBA, serves as Senior Vice President of Research for Scott & White and Assistant Dean for Research for the Division of Research & Education at the Temple Campus of the Texas A&M Health Science Center College of Medicine. As Dean, Dr. Beswick "act[s] under the authority of [Texas A&M] and [is] accountable to the College for the conduct of [his] College of Medicine activities."⁹

17. Dr. Beswick is or was in part responsible for supervising and managing the biomedical and behavioral animal research conducted at the Temple Research Facilities. His responsibilities include oversight of the compliance programs and Plaintiffs reported to him.

B. Relevant Animal Welfare Law

18. Federal law requires research facilities to develop and implement a federally-approved program designed to ensure compliance with animal welfare law.¹⁰ The law requires institutions conducting animal research to employ an attending veterinarian (hereinafter "Attending Veterinarian"), an appropriately experienced and educated person assigned the authority to

OF HEALTH AND HUMAN SERVS., PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS P. 11 (2002), <http://grants.nih.gov/grants/olaw/references/PHSpolicylabanimals.pdf> [hereinafter "PHS POLICY"]; COMM. FOR THE UPDATE OF THE GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS, NATIONAL RESEARCH COUNCIL, GUIDE FOR THE CARE OF LABORATORY ANIMALS (National Academies Press 8th ed. 2010), http://www.nap.edu/openbook.php?record_id=5140&page=R1 [hereinafter "GUIDE"].

⁹ Ex. A, Affiliation Agreement p. 6.

¹⁰ PHS POLICY, *supra* note 7, at pp. 9-10; GUIDE, *supra* note 7.

“ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.”¹¹

19. Additionally, the executive officer of a research facility must appoint an Institutional Animal Care and Use Committee (“IACUC”), which also has responsibility for evaluating the treatment of animals at the facility, certifying compliance, and reporting violations to the appropriate authorities under federal law.¹²

20. At least one committee member must be a veterinarian who has program authority and responsibility.¹³ This is usually the Attending Veterinarian. Any “[p]rocedure that may cause more than momentary or slight pain or distress to the animals . . . [must] involve, in their planning, consultation with the attending veterinarian or his or her designee.”¹⁴

21. Additionally, the research institution must supply federal agencies with an Animal Welfare Assurance (hereinafter “Assurance”), signed by an individual with the requisite authority to commit the institution to compliance under the law.¹⁵ The law designates this authorized individual as the “Institutional Official.”¹⁶

22. The Assurance must commit the institution to compliance and provide details of the institution’s animal use and care program, including an identification of IACUC members and those who will participate in the implementation of the program, i.e. the line of authority.¹⁷ The

¹¹ 9 C.F.R. §§ 1.1, 2.33(a)(2).

¹² 42 U.S.C. § 289d; 7 USC § 2143 (b); 9 C.F.R. §§ 1.1, 2.31; PHS POLICY, *supra* note 7, at pp 11-13.

¹³ 9 C.F.R. § 2.31(b)(i); PHS POLICY, *supra* note 7, at p. 11.

¹⁴ 9 C.F.R. § 2.31(d)(vi)(B).

¹⁵ 9 C.F.R. §§ 1.1; PHS POLICY, *supra* note 7, at pp. 8-9.

¹⁶ 9 C.F.R. §§ 1.1; PHS POLICY, *supra* note 7, at pp. 8-9.

¹⁷ PHS POLICY, *supra* note 7, at pp. 8-9.

IACUC and the Institutional Official are required to report incidents and violations to federal authorities.¹⁸

23. Failure to satisfy federal requirements risks the suspension of research, penalties, fines, disqualification for grants, and potentially the rescission of grants.

C. The Assurance

24. The Scott & White Memorial Hospital Animal Welfare Assurance that was submitted to the federal government on or about April 9, 2010 is attached hereto as Exhibit B. By submitting this Assurance, Veterans Health Care, the Scott & White Department of Comparative Medicine Main Vivarium (Building 25), and the Cancer Research Institute Vivarium (collectively defined as “Institution” therein) assured the United States government that the Temple Research Facilities would comply with federal animal welfare law:

I, Richard Beswick, Ph.D. as named Institutional Official . . .
provide assurance that this Institution will comply with the . . .
PHS Policy. . . .¹⁹

Institutional Compliance

- A. The Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the [Guide].
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and

¹⁸ 7 U.S.C. § 2143; PHS POLICY, *supra* note 7, at p. 18; Office of Lab. Animal Welfare, Nat’l Insts. of Health, Dept. of Health and Human Servs., Notice Number NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under PHS Policy on Humane Care and Use of Laboratory Animals, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html> (“The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.”) [hereinafter “Notice on Reporting”].

¹⁹ Ex. B, Assurance, *preamble*.

collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals in accordance with the [Guide].²⁰

25. Part of the federal law to which Scott & White commits itself in the Assurance is the prohibition against retaliation for reporting violations:

No facility employee, Committee member or laboratory personnel shall be discriminated against or subject to any reprisal for reporting violations of any regulation or standard under the Act.²¹

D. Pre-2008 Veterinary Care at the Temple Research Facilities

26. Prior to 2008, the veterinary care at the Temple Research Facilities was provided through a contract with a local private practitioner who otherwise had no experience with animal laboratory research. Personnel reported that this Attending Veterinarian was rarely present and often unavailable.²²

27. The Temple Research Facilities then operated with minimal oversight and abided practices that contravened federal law. Incidents that warranted reporting went unreported. Instead of ensuring compliance, the Attending Veterinarian merely rubber-stamped research protocols without concern for the well-being of the animal subjects. Investigators routinely failed to comply with their protocols. Proper policies were not in place to address violations.

²⁰ Ex. B, Assurance, § II.

²¹ 9 C.F.R. § 2.32(c)(4); PHS POLICY, *supra* note 7, at p. 9 n. 2 (“Compliance with the USDA regulations is an absolute requirement of this Policy.”).

²² *Cf.* 9 C.F.R. § 1.1 (defining *Attending Veterinarian* as one who “has received training and/or experience in the care and management of the species being attended”); § 2.33 (requiring attending veterinarian to ensure that the AWA is complied with and to “provide adequate veterinary care to [the facility’s] animals under “formal arrangements [] include[ing] . . . regularly scheduled visits to the research facility.”).

IACUC Committee members were uninformed about the regulations and the compliance officer knew nothing of the reporting rules.

E. Drs. Lane and Blackwood

28. In early 2008, Scott & White hired Drs. Lane and Blackwood to improve upon the veterinary care, animal welfare, and deleterious non-compliance with the federal laws and regulations governing animal welfare occurring at the Temple Research Facilities.²³

29. Drs. Lane and Blackwood are highly accomplished veterinarians whose experience and expertise in laboratory animal research stands in stark contrast to the former Attending Veterinarian.

30. Drs. Lane and Blackwood both completed their respective residencies in laboratory animal medicine at the University of California, Davis, a world-renowned leader in veterinary sciences and medicine.²⁴ Dr. Lane has 15 years experience in biomedical research with a variety of species. Dr. Blackwood has 9 years experience in biomedical research with a variety of species and her professional honors include the status of Diplomate of the American College of Laboratory Medicine, the most prestigious achievement in the field of laboratory animal veterinary medicine. During their tenure at the Temple Research Facilities, Drs. Lane and Blackwood received numerous merit raises and bonuses and received no negative evaluations.

31. Scott & White engaged Dr. Lane to fulfill the duties of the Attending Veterinarian for all of the Temple Research Facilities. (Her official title at Veterans Health Care was “Veterinary

²³For the first few months of Dr. Blackwood’s employment, she provided these services solely to one researcher at the Cancer Research Institute. However, after approximately 2 or 3 months her duties were extended to the other laboratories and entities at the Temple Research Facilities.

²⁴ U.C. Davis’s veterinary program is ranked second in the United States. See U.S. NEWS & WORLD REPORT, *America’s Best Graduate Schools*, <http://grad-schools.usnews.rankingsandreviews.com/best-graduate-schools/top-health-schools/veterinarian-rankings> .

Medical Consultant.”) Scott & White engaged Dr. Blackwood to serve as Scott & White’s Senior Veterinarian and perform the same functions for Texas A&M and Veterans Health Care.

32. Dr. Lane was assigned “program authority and responsibility for the Institution’s animal care and use program” and Dr. Blackwood had “the authority to intervene in any procedure in the best interest of animal care in Dr. Lane’s absence.”²⁵

33. Drs. Lane and Blackwood were the only two veterinarians to serve on the IACUCs of Scott & White, Texas A&M, and Veterans Health Care.²⁶

F. Non-Retaliation Promise

34. In accordance with federal law and the Assurance provided to federal authorities,²⁷ Scott & White promised its employees that none would suffer retaliation for reporting violations of animal welfare law or policy. Scott & White delivered to Drs. Lane and Blackwood a one-page memorandum that in pertinent parts reads as follows:

Scott & White expects all staff to use good judgment when making decisions regarding compliance issues for animal care and use. The NIH Guide and Scott & White Assurances provides broad direction for doing this. . . . If you believe that a violation of policy or law was committed, you are obligated to report it. . . . If you believe the issue is not properly addressed, you must take your concern to the next level of management.

To encourage appropriate use of this reporting procedure, Scott & White has a non-retaliation policy that strictly prohibits any kind of retaliation or retribution against any employee who, in good faith, contacts their supervisor or institutional officials. All staff are treated with dignity and respect.²⁸

²⁵ Ex. B, Assurance at § III.B.

²⁶ Ex. B, Assurance at p. 15.

²⁷ 9 C.F.R. § 2.32(c)(4); Ex. B, Assurance at preamble and § II.

²⁸ Scott & White Problem Resolution Process for Animal Care and Use Program, attached hereto as Exhibit C.

35. This non-retaliation policy was also posted in every animal laboratory and housing area at the Temple Research Facilities.

G. Retaliation

36. Unsurprisingly, not all investigators took kindly to the increased compliance efforts. Drs. Lane and Blackwood encountered researchers who were unacquainted with the laws and regulations and hostile when compliance was requested of them. Investigators generally behaved aggressively and unprofessionally towards the doctors' attempts to bring about compliance. When Drs. Lane and Blackwood attempted to rectify deficiencies they were berated, yelled at, disregarded, and ultimately subjected to reprisals.

1. Researcher A

37. In early 2008, a Researcher A²⁹ had mice that developed ulcerative dermatitis. This condition is not uncommon for the particular type of mice Researcher A was working with and treatment is often unsuccessful. When Drs. Lane and Blackwood attempted to address concerns over the welfare of the animals, Researcher A flew into a rage and assaulted Dr. Blackwood. He implied that Dr. Blackwood did not know how to care for this condition. In response to her questions and directions regarding the care of the mice, he yelled in her face: "I pay your salary!" Dr. Lane had to escort him out of the animal room to end the aggressive attack on Dr. Blackwood.

2. Researcher B

38. Another example of noncompliance that led to verbal abuse was that of Researcher B's overcrowded cages. The Guide establishes specific requirements for the sizes and occupancy rates of cages for various animals. Because many upkeep services are billed by the cage,

²⁹ The names of individual researchers have been omitted and they are identified here by letter.

investigators are incentivized to place as many animals in one cage as possible. Researcher B was a consistent offender.

39. Dr. Blackwood had repeatedly told Researcher B that he needed to abide by the standards for cage occupancy. Nonetheless, he continued to flagrantly violate the rules. Dr. Blackwood finally became exasperated with Researcher B's noncompliance and when she told him that the overcrowding would no longer be tolerated, he became hysterical and exclaimed in outrage that that he did not have to do it at Cornell.

40. Apparently Researcher B thought it audacious that Drs. Lane and Blackwood would demand compliance with the Guide and once demonstratively commented at a meeting: "The Guide is a 'gold standard' and is way up here . . . and we need to be [down] here!"

3. *Researcher C*

41. One incident with a Researcher C evinces a callous disregard for the animals altogether. The euthanizing of animals is stringently regulated. One day, Researcher C indicated he needed to euthanize one mouse and was given the proper dosage. The dosage is important; too little and the mouse may not expire and thus would needlessly suffer.

42. For some reason Researcher C decided to euthanize three mice instead of one. However, in lieu of going back down to the office to retrieve two more doses, he opted for divvying up the one dose amongst the three mice. He then placed the mice in the freezer, as is customarily done with the carcasses. Later that day Dr. Blackwood had the shocking experience of finding the three mice still alive inside in the freezer.

43. Dr. Lane was notified right away and she called Researcher C to inform him of what they had found and confirm that he had only used the single dose on all three mice. He was reluctant

to speak but did confirm that this was the case. Dr. Lane calmly informed him that this would have to be reported to the IACUC.

44. When a formal meeting was convened to discuss the incident, Researcher C was silent, allowing his department chair to expound on his absolute compliance with all regulations. When Dr. Lane indicated that this was not the case in this instance and that this was something to be taken seriously, Researcher C shouted that Dr. Lane was “unstable.” The chair then went on to complain that the IACUC interfered with research. No attempt was made to redirect the discussion to the violations at issue.

4. Researcher D

45. In May of 2011, Drs. Lane and Blackwood came across a very serious and significant violation. Researcher D was conducting or participating in what is known as a *category E* study. A category E study is research for which death is an end point or when pain cannot be alleviated with analgesics. Category E studies are rare and to obtain approval an investigator must present considerable justification. In this case, the category E study had been approved for 40 animals.

46. However, in late May, Drs. Lane and Blackwood discovered that the study was being conducted on far more than the 40 approved animals. Upon review of the post-operative records, Drs. Lane and Blackwood found that approximately 110 animals had been subjected to the study. The investigator had not obtained approval for more than 40 animals on the protocol. Indeed, the additional animals had not in any way been reported to the IACUC. In accordance with the PHS Policy and their obligations, Drs. Lane and Blackwood reported this protocol violation to the IACUC.

5. Termination

47. Initially, Dr. Beswick disregarded Drs. Lane and Blackwood's concerns, both about the harassment and the attitudes of researchers. He stated that the researchers simply liked to "whine and bitch" and relayed that he "wouldn't worry about it too much" because "[they] knew the real deal," i.e. that Drs. Lane and Blackwood were only doing what they were required to do by law.

48. Dr. Beswick's perspective changed. On July 5, 2011, Dr. Beswick called Dr. Lane into his office and told her that she was being demoted because she was unqualified.

49. Additionally, Dr. Beswick told Dr. Lane that Dr. Blackwood was being terminated because she was too strict and aggressive regarding compliance and reporting. Dr. Beswick alluded specifically to the incident involving Researcher D's study as an example of the reporting for which she was being terminated.

50. Scott & White's promulgated policies dictate that human resources should be consulted prior to any disciplinary action affecting employment status; it appears that this protocol was not followed. A copy of said policies are attached hereto as Exhibit D.

51. Later that day, Dr. Beswick called Dr. Blackwood into his office. Despite Dr. Beswick's prior representations to Dr. Lane, he told Dr. Blackwood she was being terminated because she was not properly qualified. He said that he would not discuss it any further and did not need to explain.

52. At the time of the termination Dr. Lane had been offered a position at Harvard University in Boston, Massachusetts. On July 5, 2011, she had not yet made up her mind as to whether or not she would accept. The position came with less pay and a dramatic increase in the cost of living. On or about July 14, 2011, Dr. Beswick asked Dr. Lane to identify her last day. She

responded that she had not yet resigned. Dr. Beswick indicated that her “verbal” resignation had been accepted. On July 15, 2011, she was asked to leave the premises immediately.

53. On July 15, 2011, the Temple Research Facilities were without an appointed Attending Veterinarian, a condition which under the law would require the facilities to immediately suspend all animal research. Finding that untenable, Dr. Beswick called Dr. Blackwood into his office and insisted that she take on the Attending-Veterinarian duties until a permanent replacement could be found. He nonetheless confirmed that she was still terminated and again expressed the opinion that she was too aggressive regarding compliance. He asked that she “[b]e a little gentler with them;” “them” being the researchers. Dr. Beswick also indicated that he might reconsider her termination if, in the next few months, the researchers accepted her. He implied that her purportedly aggressive enforcement efforts may have been a result of Dr. Lane’s encouragement.

54. Dr. Blackwood indicated that she would require additional consideration for the work being asked of her and such sums were subsequently demanded but not received. Dr. Blackwood nonetheless served as interim Attending Veterinarian. On January 15, 2012, despite still being listed as the official Attending Veterinarian, Dr. Blackwood was denied entry to the premises, a clear violation of the law.

55. As a result of Defendants’ misconduct, Plaintiffs have suffered economic injury, emotional distress, and damage to their reputations.

IV. CAUSES OF ACTION

A. Breach of Contract

56. Plaintiffs had valid and enforceable employment contracts.

57. Plaintiffs' contracts limited Scott & White's ability to terminate Plaintiffs because they strictly prohibited retaliation or retribution for reporting violations of animal welfare law or policy.

58. Plaintiffs performed or tendered performance of their contractual obligations, or their performance was excused or waived.

59. Defendant Scott & White breached the contracts by retaliating against Plaintiffs for reporting violations of animal welfare law or policy.

60. Scott & White's breaches caused the Plaintiffs injury.

B. Section 1983

61. Plaintiffs had a protected property interest in continued employment with Scott & White, Texas A&M, and Veterans Health Care in accordance with the agreed upon terms.

62. Defendants Beswick, Assistant Dean for Research for the Division of Research & Education at the Temple Campus of the Texas A&M Health Science Center College of Medicine, is a state actor.

63. Scott & White was a willful participant in joint activity with Texas A&M and Dr. Beswick acted in concert therewith to deprive Plaintiffs of their constitutional rights.

64. In virtue of Scott & White's identity, entwinement, and/or joint activity with a state actor, their conduct constitutes state action and can fairly be attributed to the state.

65. In virtue of the close nexus between the state and the challenged conduct, Scott & White's behavior may fairly be treated as the behavior of the state itself.

66. Defendants violated Plaintiffs' Fourteenth Amendment substantive due process rights when, acting under the color of state law, they arbitrarily or capriciously terminated Drs. Blackwood and Lane.

67. Defendants violated Plaintiffs' Fourteenth Amendment procedural due process rights when, acting under the color of state law, they terminated Plaintiffs without affording them meaningful notice and an opportunity to be heard at a meaningful time and in a meaningful manner.

68. Defendants intentionally so deprived Plaintiffs of their constitutional rights or acted with a reckless or callous disregard of or indifference to Plaintiffs' rights.

69. Defendants' termination of Plaintiffs was not objectively reasonable in light clearly established law.

70. Pursuant to 42 U.S.C. § 1983, Defendants are liable to Plaintiffs for both compensatory and punitive damages.

C. *Quantum Meruit*

71. Plaintiff Blackwood provided valuable services to Scott & White in the form of additional duties taken on during her appointment as interim Attending Veterinarian.

72. Scott & White accepted and benefited from Dr. Blackwood's additional services.

73. Scott & White had reasonable notice of her expectation for additional consideration.

74. Scott & White has wholly failed to compensate Dr. Blackwood for the additional services to which she is entitled to.

D. *Attorney's Fees*

75. Plaintiffs seek attorney's fees pursuant to 42 U.S.C. § 1988 and Texas Civil Practice and Remedies §§ 38.001, *et seq.*

V. CONDITIONS PRECEDENT

76. All conditions precedent to Plaintiffs' right to recovery have been performed, occurred, or been waived or excused.

VI. JURY TRIAL

77. Plaintiffs have demanded trial by jury.

VII. PRAYER

78. Plaintiffs pray for judgment against the Defendants and an award of all actual, general, specific, and consequential damages; all special, punitive, and exemplary damages; pre- and post-judgment interest; attorney's fees and costs; and all such other and further relief, whether at law or in equity, to which Plaintiffs may show themselves justly entitled.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

The undersigned hereby certifies a copy of the foregoing was served on counsel for Defendants via the Court's CM/ECF system and electronic mail on this the 16th day of October, 2012.

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/s/ Isabelle M. Antongiorgi
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AFFILIATION AGREEMENT
· BETWEEN
THE TEXAS A&M UNIVERSITY SYSTEM
AND
SCOTT & WHITE CLINIC; SCOTT AND WHITE MEMORIAL HOSPITAL AND SCOTT,
SHERWOOD AND BRINDLEY FOUNDATION
AND
THE CENTRAL TEXAS VETERANS HEALTH CARE SYSTEM

This agreement is made and entered into this 24th day of August 2000 by and among The Texas A&M University System, a State agency, on behalf of the Health Science Center College of Medicine (HSC-CoM) hereinafter referred to as TAMUS, the Scott & White Clinic, a Texas nonprofit corporation, and Scott and White Memorial Hospital and Scott, Sherwood and Brindley Foundation, a nonprofit Texas corporation located at Temple, Texas and both hereinafter referred to in singular as Scott and White, and the Central Texas Veterans Health Care System, a federal agency, hereinafter referred to as the CTVHCS.

Scott and White has for over one hundred years evidenced leadership in the delivery of quality patient care, and community service, enhanced by research and education.

TAMUS components established in the 20th Century a reputation for quality education, research and public service.

The CTVHCS has, since the establishment of the TAMU College of Medicine, played a key role in the operation of medical education and research programs.

For twenty-four years, TAMUS, Scott and White, and the Olin E. Teague Veterans Center, have successfully operated an accredited medical school under the name of "The Texas A&M University College of Medicine" using Scott and White's Temple campus and the Olin E. Teague Veterans Center as the core clinical campus and primary teaching facility of the College of Medicine.

TAMUS, HSC-CoM, Scott and White and the CTVHCS affirm that they desire to continue their collaborative efforts and reaffirm their affiliation for the attainment of excellence in:

- (1) the advancement of medical service through comprehensive high quality patient care;
- (2) education of medical and allied health professionals;
- (3) advancement of medical knowledge through investigation and publication of the results; and
- (4) promotion of personal and community health.

TAMUS, Scott and White and the CTVHCS wish to further express the following agreement:

- (1) TAMUS HSC shall retain all jurisdictional powers incident to separate ownership, including the power to determine the general and fiscal policy of the TAMUS HSC, the selection of its administration, faculty and staff personnel, and the assignment of students to its current or future campuses.
- (2) Scott and White shall retain all jurisdictional powers incident to separate ownership, including the power to determine the general and fiscal policy of Scott and White, selection of its administrative staff, and Scott and White shall be the sole determiner of appointments to its medical staff.
- (3) The CTVHCS shall retain all jurisdictional powers incident to separate ownership, including the power to determine the general and fiscal policy of the CTVHCS, selection of its administrative staff, and shall be the sole determiner of appointments to its medical staff.
- (4) To the fullest extent possible under Federal and State law, TAMUS HSC-CoM, Scott and White and the CTVHCS commit to carry out the provisions of this affiliation and the shared missions of education, research and service

- (5) This non-exclusive agreement is for mutual cooperation for public benefit and does not create a relationship between the parties as a legal partnership, joint venture, association, employer/employee, principal/agent, lessor/lessee or any similar legal relationship. TAMUS HSC, Scott and White and the CTVHCS shall continue to act as independent contractors within the CoM's shared missions of education, research and service.

Within the constraints of federal law, state law and regulations, TAMUS HSC-CoM, Scott and White and the CTVHCS shall seek to achieve shared governance and responsibility for undergraduate education, residency and fellowship programs, allied health instruction, continuing education and research activities.

TAMUS HSC, Scott and White and the CTVHCS recognize that they are responsible for their respective agents and employees and each hereby indemnifies the other against all claims and liabilities of every kind rising out of the acts and omissions of its agents and employees, as each party is authorized by law.

COMMITMENT

TAMUS HSC-CoM agrees to provide academic leadership and appropriate appointment to the faculty for Scott and White and the CTVHCS physicians and staff involved in education, research and public service programs, and to provide leadership and support for research activities that mutually benefit Scott and White, TAMUS HSC-CoM and the CTVHCS.

TAMUS HSC agrees to provide access for Scott and White and the CTVHCS personnel to HSC facilities, programs, telecommunication and video capabilities, library resources, and any other such services as may be developed, consistent with Federal, State and HSC policy

Scott and White and the CTVHCS agree to provide their physician staff and other health personnel, appropriate space and access to its varied clinical populations for the purpose of academic instruction and, where appropriate, research.

Scott and White and the CTVHCS agree to provide clinicians, scientists and support for the conduct of the education and research programs of the TAMUS HSC-CoM.

USE OF NAME AND TRADEMARKS

To indicate the full partnership and commitment of all three partners to the missions of the HSC-College of Medicine, a logo incorporating each partner and the name "College of Medicine" shall be developed for use in all communications and activities of the College of Medicine and for those activities with a shared commitment and responsibility.

TAMUS HSC-CoM, Scott and White and the CTVHCS may describe their affiliation and cooperative programs in a fair and equitable manner consistent with this affiliation agreement. Personnel who carry appointment to the faculty or administrative staff of the College of Medicine may publicly identify their positions consistent with TAMUS Regulations and HSC rules in the same manner as all other faculty and administrative staff of the TAMUS Health Science Center.

PLANNING AND PROGRAM DEVELOPMENT

Strategic planning is an essential part of the development of the HSC College of Medicine. Because the success and future of the TAMUS HSC-CoM, Scott and White and CTVHCS are intertwined, programs and planning shall be conducted as a joint activity. Ongoing planning and annual review of the plan will move the College of Medicine to a greater academic prominence, both in Texas and the nation. Planning should encompass departments, programs, and institutes as well

as funding for infrastructure, faculty and operations. The formal planning process should be done annually taking into consideration budget cycles and legislative calendars of all parties.

TAMUS HSC-CoM, Scott and White and the CTVHCS agree to establish a Strategic Planning Task Force by January 1, 2001 to examine strategy for achieving a fully integrated College of Medicine.

The development of new HSC-CoM programs, departments, institutes and centers, colleges, additional campuses or training sites shall be developed with the consensus of all three parties; then shall be approved under the procedures established by The Texas Legislature, The Texas A&M University System, The Texas Higher Education Coordinating Board, and other State agencies.

Each party (HSC, Scott and White and the CTVHCS) may have independent professional programs that fall outside this Agreement.

FACULTY

Appointment to the faculty of TAMUS HSC-CoM shall be the prerogative of TAMUS HSC-CoM under appropriate TAMUS Regulations and HSC Rules. Scott and White and the CTVHCS personnel appointed to or promoted in the faculty shall meet HSC-CoM requirements, with respect to appropriate academic qualifications. The process for faculty appointment will be consistent with national standards. Faculty appointments will be based upon total contributions to the HSC-CoM, including all educational and research activities, and patient care related to instructing and mentoring students and residents, and community outreach and public service. It is recognized that contributions will be different for the basic science and the clinical departments as they have different responsibilities in order to accomplish progressive educational skills for professional students. Faculty responsibilities will be delineated upon appointment. Accountability of faculty will be

measured by annual evaluation of faculty performance by department heads in consultation with the Dean, HSC-CoM. Joint appointment between basic science and clinical departments is encouraged in order to support the total program of the HSC-CoM. Faculty residing at any campus of the College of Medicine shall to the extent allowed by state law, have rights, privileges and responsibilities to serve in the administrative structure and educational programs of the College of Medicine.

ADMINISTRATIVE OFFICIALS AND DEPARTMENT HEADS

Administrative officials (Dean, Associate and Assistant Deans, Department Heads and Center and Institute Directors) will act under the authority of the HSC-CoM and are accountable to the College for the conduct of their College of Medicine activities. Appointment of administrative officials for the College of Medicine and its related programs is the responsibility of the President of the Health Science Center, upon the recommendation of the Dean of the College of Medicine, after consultation with the clinical parties.

Job/role descriptions for administrative officials and department heads will include a commitment to achieving excellence in education/teaching, research, and clinical service/outreach. Such job/role descriptions will include measurable objectives toward achieving such goals. Original appointment and subsequent reappointment of administrative officials and department heads will be based upon demonstrated success in achieving the measurable objectives and advancing the goals of excellence in all academic matters in their department or area of responsibility.

TAMUS HSC-CoM, Scott and White and the CTVHCS agree that all clinical department chairs and division directors will be located on the clinical campuses in Temple, once approved through the College of Medicine administrative procedures. As part of this affiliation agreement, the

existing clinical department heads/chairs and division directors/chairs shall retain their current positions.

Upon the occurrence of a vacancy for department head/chair and with the concurrence of all three parties, the Dean shall appoint a search committee. Upon completion of the search, the committee shall recommend one or more candidates to the Dean to fill the positions. The Dean shall, after concurrence with the Scott and White and CTVHCS CEO's, recommend to the HSC the consensus candidate to fill the department head/chair. Both search/appointment and periodic performance review will be based upon the job description.

The Dean, or the CEO of either Scott and White or the CTVHCS, shall have the prerogative to request the replacement of a clinical department chair or division head. Such replacement shall occur only after consultation and agreement among the parties. When such replacement is being contemplated the parties to this agreement will make a sincere effort to resolve whatever difficulty might exist through a joint conference of the Dean and the CEO's.

For those departments where no clinical service exists at the CTVHCS, concurrence of only Scott and White and the Dean will be required for the processes described in the above two paragraphs.

There shall always be, administratively, only one academic department for each discipline, regardless of the number of instructional sites. For those departments which have multiple clinical sites, an appropriate physician may be designated as an academic Vice Chair or Regional Chair.

The CTVHCS Chief of Staff will also carry the title of Associate Dean for Veterans' Affairs or other academic appointment, title, or responsibilities as appropriate. This position, as well as that of other key clinical administrative officials, who have a scope of responsibility across departments, will be approved by the appropriate CEO after consultation with the CEOs of the other parties. A VA

Dean's Committee and a VA Dean's Executive Committee will meet regularly to review and assure support for, and quality of, academic programs at the CTVHCS.

RESIDENCY AND FELLOWSHIP PROGRAM

Scott and White, TAMUS HSC-CoM and the CTVHCS agree to jointly sponsor and operate residency and fellowship training programs as mutually agreed. All such residency and fellowship training programs shall be known as Texas A&M University System HCS-College of Medicine-Scott and White Graduate Medical Education Programs:

- (1) Scott and White shall provide the following services for the establishment and operation of the Graduate Medical Education programs.
 - A. Administrative support including, but not limited to, payroll administration, correspondence with national accrediting bodies, monitoring of licensure requirements, correspondence with applicants, and further services as required.
 - B. Facilities and patients necessary to support a Residency Review Council approved residency program.
 - C. Funding for that portion of the cost of graduate medical education programs not covered by appropriation from the Legislature of the State of Texas through the medical school.
- (2) TAMUS HSC-CoM shall provide the following:
 - A. Appropriate certification of faculty members who function in instructional roles in the program.

- B. The Dean shall be an *ex-officio* , non-voting member of the Board of Trustees of Scott and White Memorial Hospital and Scott, Sherwood and Brindley Foundation.
 - C. Appointment of Residency Program Directors shall be jointly approved through administrative procedures established by Scott and White and the Dean of the College of Medicine.
- (3) Because the GME programs serve both an academic and clinical purpose, the management of the Graduate Education Program shall be the shared responsibility of TAMUS HSC-CoM, CTVHCS and Scott and White. The Department Heads of the academic clinical departments (including the Clinical Chairman of Pathology at Scott and White) shall have the following duties, being delegated from the Dean and from the Board of Trustees of Scott and White Memorial Hospital and Scott, Sherwood and Brindley Foundation as well as the Board of Directors of Scott and White Clinic.
- A. Recruitment, appointment and evaluation of residents.
 - B. Recruitment and evaluation of GME faculty responsible for resident and fellow training.
 - C. Supervision of resident patient care activities.
 - D. Development and implementation of a curriculum appropriate to residency training.
- (4) Appointments to the positions of resident physicians or fellows within the TAMUS HSC-College of Medicine/Scott and White Graduate Education Program shall be the responsibility of Department Heads and Program Directors and shall be ratified by the Dean of the College of Medicine.

PUBLIC AFFAIRS

TAMUS HSC-CoM, the CTVHCS and Scott and White, in recognition of the public value of this affiliation, agree to coordinated efforts of public information that appropriately describe activities and assets resulting from the affiliation. The appropriate officials from each organization will work closely in this cooperative effort. Each institution shall, however, remain free to conduct its own public relations and information campaigns for its separate activities that do not imply approval of the other or represent unfair or inappropriate use of the affiliation.

DEVELOPMENT ACTIVITIES

TAMUS HSC-CoM, Scott and White, and CTVHCS agree to pursue opportunities to collaborate in development activities when such activities directly benefit the affiliated institutions' abilities to support the mission of the College of Medicine. All collaborative efforts will be program focused and mutually agreed upon in advance by TAMUS HSC-CoM, Scott and White and CTVHCS.

SHARED ASSURANCES

Scott and White, TAMUS HSC-CoM and the CTVHCS agree to cooperate in providing assurances to the various constituencies in a unified manner. TAMUS HSC-CoM, Scott and White and the CTVHCS expressly agree to use their respective mechanisms of assurance for the benefit of mutual programs and where possible to eliminate duplication. Specifically, every effort will be made to establish a single Temple Institutional Review Board for studies with human subjects that can represent Scott and White, TAMUS HSC-CoM, CTVHCS and other entities as may participate in the medical research programs to their respective publics.

RESEARCH

Since research enhancement will be a strategic goal of the three parties, measurable outcomes will include:

- (1) extramural research funding in the clinical and basic science departments,
- (2) faculty time specifically committed to research activities,
- (3) peer reviewed publications, and
- (4) funding and resources committed by each of the parties to the research enterprise

TAMUS HSC CoM, Scott and White and the CTVHCS acknowledge the value of joint participation in research projects and would ultimately hope to achieve full integration of research activities of their institutions (the Addendum to Affiliation Agreement is attached as an exhibit and is an integral part of this Affiliation Agreement). With that goal in mind, the three institutions will establish equivalent and, when practical, common peer review mechanisms for scientific review of research protocols, whether funded by TAMUS HSC-CoM, Scott and White, the CTVHCS or other entities. In joint research applications, appropriate and equitable arrangements will be negotiated for sharing of resources.

Research applications submitted for competitive funding to any outside entity from Scott and White or the CTVHCS which use the TAMUS HSC-CoM relationship or the faculty status of their clinician staff as an integral part of the application must have the approval of the Dean through the designated Associate Dean on the Temple campus upon the recommendation of the department head and the appropriate peer review group. The CTVHCS and Scott and White will regularly inform the Dean of all applications for research activity which use the faculty status of their clinician staff as a part of the application.

Scott and White, TAMUS HSC-CoM, and the CTVHCS will jointly seek to assure that all research efforts carried out by Temple-based faculty, regardless of funding source or administrative oversight, will be acknowledged as TAMUS HSC-CoM research activity for appropriate reporting to the state legislature, LCME, AAMC, and other relevant oversight bodies.

CONTRACT

Scott and White and TAMUS HSC shall annually execute a contract for payment of services provided to TAMUS HSC-CoM by Scott and White. Such a contract shall take into consideration the value, both tangible and intangible, of the relationship to Scott and White and to TAMUS HSC-CoM.

TERMS

This agreement shall be for a 25 year term beginning on the date of the final signature on the agreement. The parties agree to an annual review of progress on specific outcome measures, including periodic review of the agreement by all three parties with active reaffirmation or agreement on revisions.

During the period of annual and periodic reviews, issues of concern should be raised and every opportunity for resolving such concerns should be explored. If meaningful efforts to resolve substantial concerns cannot be resolved over time, the agreement may be terminated by any party except any party must provide notice to the other two parties. Such written notice must assure that educational commitments to students are met for a period of not less than 5 years. In the event of termination, all students then enrolled or officially accepted into programs

of the TAMUS Health Science Center College of Medicine shall have the right to complete their degrees under conditions promulgated in the official publications of TAMUS HSC-CoM.

Executed in triplicate originals on the 24th day of August, 2000.

Recommended:




President, TAMUS HSC



Dean, TAMUS HSC-College of Medicine

The Texas A&M University System

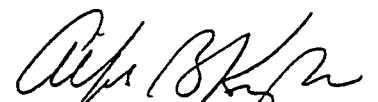
 8/18/2000

Howard D. Graves (date)
Chancellor

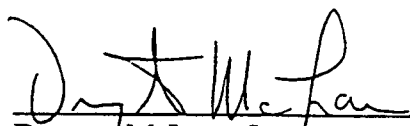
 8/24/00

Don Powell (date)
Chairman of the Board of Regents

Scott and White

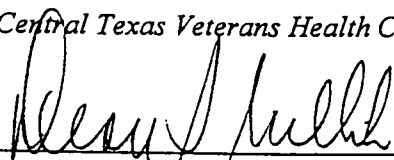
 8/19/00

Alfred B. Knight, M.D. (date)
CEO and President

 8/19/00

Drayton McLane, Jr. (date)
Chairman of the Board

Central Texas Veterans Health Care System

 8-21-00

Dean Billik (date)
Director

Scott & White Memorial Hospital
A3895-01
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, Richard Beswick, Ph.D. as named Institutional Official for animal care and use at Scott & White Memorial Hospital, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live vertebrate animals supported by the Public Health Service (PHS) and conducted at this Institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or -supported activity by this Institution.

"Institution" includes the following branches and major components of Scott & White Memorial Hospital:

Scott and White Department of Comparative Medicine Main Vivarium (Building 25) and the Cancer Research Institute (CRI) Vivarium. There are two animal facilities at Scott & White that provide animal housing and procedure space. Building 25 has a total of 10,252 square feet including animal housing, surgery suites, necropsy, procedure rooms, cage wash, support areas, and an ABSL-2 housing/procedure suite. The annex building adjacent to building 25 provides 640 square feet of housing only. The Cancer Research Institute (CRI) Vivarium has 1,322 square feet including animal housing and procedure areas.

The Central Texas Veterans Health Care System ((CTVHCS) an integration of VA Hospitals in Temple, Waco, and Austin) has a research building (Building 205) located on the CTVHCS campus in Temple. This institution is approximately 1 ½ miles from the Scott and White campus. As the CTVHCS does not have an animal facility, the Scott & White Department of Comparative Medicine provides animal housing and research support. Rodents are transported as needed from Scott & White to research laboratory space at CTVHCS building 205. No animals remain for more than 24 hours at this location. This research building is covered under the Scott & White IACUC, AAALAC Accreditation, USDA License, and OLAW Assurance.

"Institution" also includes the following: n/a

II. INSTITUTIONAL COMMITMENT

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use

of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" ("Guide").

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows:

Attachment A: Organizational Chart

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: Jennifer Lane

Qualifications:

- Degrees: D.V.M.
- Training and/or experience in laboratory animal medicine:

Dr. Lane completed a residency in Primate Medicine at the California National Primate Research Center, University of California-Davis. She has over 13 years of experience in the laboratory animal field and has worked with a variety of species (rodents, rabbits, ferrets, swine, sheep, dogs, great apes, old and new world monkeys).

Authority: Dr. Lane has delegated program authority and responsibility for the Institution's animal care and use program. Dr. Lane is the Attending Veterinarian for Scott & White, and the Texas A&M Health Science Center (TAMHSC) on the Temple campus. She also serves as Director of the Department of Comparative Medicine at Scott & White.

Time Contributed to Program: Full time employee. 100% of time is dedicated to the animal care and use program.

Name: Rebecca Blackwood

Qualifications:

- Degrees: D.V.M.
- Training and/or experience in laboratory animal medicine:

Dr. Blackwood completed a residency in Laboratory Animal Medicine at the University of California-Davis. She is ACLAM Board Eligible and has 9 years experience in the laboratory animal field.

Responsibilities: Dr. Blackwood is the Senior Veterinarian for Scott & White and TAMHSC-Temple Campus. She also serves as Associate Director of the Department of Comparative Medicine and assists with all aspects of the Animal Care Program. She is appointed as Dr. Lane's alternate on the IACUC committee. Dr. Blackwood is the primary provider of clinical care for the program. She has the authority to intervene in any procedure in the best interest of animal care in Dr. Lane's absence.

Time Contributed to Program: Full time employee. 100% of time is dedicated to the animal care and use program.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

1. Review at least once every six months the Institution's program for humane care and use of animals, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

Review of the animal care and use program is conducted semiannually (May and November) with a minimum of two IACUC members present at each component of the review. All members of the IACUC are invited to participate in the semiannual program inspections. During the review, a checklist is provided as a guide for inspection of program processes. The "Guide" and OLAW sample check lists are used as a basis for these evaluations. Protocol files, regulation and policy statements, current licenses and documents, are reviewed in the IACUC office. The IACUC inspection of the animal use program includes the IACUC office, veterinary care and program administration, occupational health, and safety training. Notes from the reviewers are combined into a report along with the inspection of the institution's animal facilities. The report is reviewed and discussed by the full committee at the following IACUC meeting. After discussion, the IACUC votes on the approval of the report and signs a consent of approval. Any minor discrepancies are forwarded to the appropriate persons or departments for correction within a specified time frame with documentation. The report is submitted to the Institutional Official who acknowledges receipt of the report with a memo. If any incidents or major discrepancies are discovered during the inspection, the IACUC follows the Federal, State, and local regulations as required and outlined in the USDA Animal Welfare Act and the PHS Policy.

2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

Review of the animal care and use program is conducted semiannually (May and November) with a minimum of two IACUC members present at each component of the review. All member of the IACUC are invited to participate in the semiannual facility inspections. During the review, a checklist is provided as a guide for inspection of physical facilities and program processes. The "Guide" and OLAW sample checklists are used as a basis for these evaluations. IACUC members inspect the facility, to include animal study areas, transport vehicles, holding rooms, procedure rooms, and storage rooms. Investigator labs and animal holding rooms are inspected at the CRI and CTVHCS Research Building 205. Notes from the reviewers are combined into a report along with the inspection of the institution's program for humane care and use of animals. The report is reviewed and discussed by the full committee at the following IACUC meeting. After discussion, the IACUC votes on the approval of the report and signs a consent of approval. Any minor discrepancies are forwarded to the appropriate persons or departments for correction within a specified time frame with documentation. The report is submitted to the Institutional Official who acknowledges receipt of the report with a memo. If any incidents or major discrepancies are discovered during the inspection, the IACUC follows the Federal, State, and local regulations as required and outlined in the USDA Animal Welfare Act and the PHS Policy.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

Semiannual reports and meeting minutes are reviewed by full committee for approval and actions. Any deficiencies, minor or significant, are forwarded to the appropriate persons or departments for corrective action within specified time frame and documentation of corrective actions. The Semiannual Reports identify deficiencies, categorize them as minor or significant, and include a plan and schedule for correction of each deficiency. The IACUC follows the Federal, State, and local regulations as required and outlined in the USDA Animal Welfare Act and the PHS Policy. The semiannual report is signed by a majority of the IACUC members and identifies any minority opinions or views expressed by committee members. The semiannual reports and meeting minutes are submitted to the Institutional Official who acknowledges receipt with a memo.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

All individuals entering the facility or working with animals are trained to use an incident report form to report any concern. These forms and the process for reporting concerns are provided during the initial training presentation and are posted on doors throughout the facility with phone numbers, email address for the Attending Veterinarian, IACUC Chair, Institutional Official, and anonymous report contact number. The form or report of incident is submitted to the IACUC office and Chair of the IACUC who immediately consults the IACUC, Attending Veterinarian, and/or other employees concerning care and welfare of the animals. Any deficiencies will be corrected promptly and prompt disciplinary action will be taken regarding any employee or cooperator found to have negatively affected the welfare of the animals. An individual reporting a concern will be provided protection against reprisal as required under the Animal Welfare Act and Scott & White Policy manual. The incident and associated resolution go through full committee review. The incident along with the IACUC findings and recommendations are reported to the Institutional Official who will arrange for any additional appropriate review, reporting and action.

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

Report of incidents or deficiencies are reviewed by the full IACUC for approval and recommendation of actions. The semiannual reports also list any deficiencies, categorizes them as minor or major and includes a plan and schedule for correction for all deficiencies noted. The process used to correct deficiencies is to notify the investigator or the facility in writing of the deficiencies and a time line for correction. Inspection reports, along with indications of corrective actions, are submitted to the Institutional Official. During IACUC periodic reviews of policies, procedures and operations, additional items and requests are transmitted in writing to the IO for review and action.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

The IACUC office receives the animal use protocol (AUP) and, if a grant application is involved, a copy of the grant is required. An identification number is assigned to the package. The AUP is reviewed for any missing information, signatures, approval from safety officials, etc. The Operations Manager pre-

screens the AUP and signs a statement in the AUP that the animal species, the special requirements for housing, and the number of animals to be housed can be accommodated by the facilities. The Attending Veterinarian pre-screens the AUP and signs a statement in the AUP that the protocol addresses analgesic and anesthetic use, surgery, animal care, and euthanasia using acceptable veterinary practices and agents. This screening and signature process ensures that investigators interact with both the Operations Manager and the Attending Veterinarian during the development of an animal use protocol. The process does not assure that these individuals or other members of the IACUC will approve the protocol during either full committee review or a designated member review, if such is performed. Both the AUP and grant are sent to the IACUC members for review. If any hazardous agents are used, the MSDS is attached, reviewed and approved by the appropriate Health and Safety Committees and officers prior to final IACUC approval.

For full committee review (FCR), the application proposal is brought to a convened meeting of the IACUC with a quorum present. IACUC members who have a conflict of interest regarding a protocol may participate in discussion, but must leave the room during the final discussion and voting for that protocol. There are three possible outcomes for FCR: 1) Approval, 2) proposal requires additional modifications or revision to secure approval, and 3) disapproval. A protocol may be tabled with the vote of a majority of IACUC members until additional information is obtained to allow assessment into one of these three outcomes. Minutes of the IACUC meeting are provided to the Institutional Official.

If the application is approved, then an approval memo is sent to the principal investigator. The approval memorandum provides the numbers and descriptions of animals that are allowed. This notice is copied to the Operations Manager and Attending Veterinarian as all orders are arranged through these individuals. Investigators are allowed to initiate the ordering of animals and their study when they receive this official approval. They do not need to acknowledge receipt of an approval memo prior to initiating orders or their work. Investigators may not order animals without this approval. Investigators with labs located at the CTVHCS or have VA funds may not begin new animal studies until they have received final written approval from the Associate Chief of Staff for Research and all applicable committees and subcommittees at the CTVHCS.

If modifications to a proposal are needed to obtain approval, investigators are notified by memorandum listing the issues and required modifications. They must respond to this request to have a revised proposal reviewed. In this situation, investigators are not allowed to order animals or initiate any animal activities.

The IACUC has approved, in writing, a process for designated member review (DMR) that can be used when a proposal requires additional modifications or clarifications. If during the full committee review a proposal will require modifications or clarifications in order to obtain approval, a motion can be made to send the proposal to DMR. The motion requires a unanimous vote of those members present. In this circumstance, the motion may state that a designated review can be performed provided that the revised proposal is first posted on the IACUC website for all committee members to view for 48 hours. Any member may request, upon examining the revised proposal, that it return to the full committee for action. During the designated review, the reviewer may either approve the revised proposal or send it to the full committee for action. The result of this designated member review process is reported in a memorandum to the investigator. Again, only if an approval memo is sent to the investigator may animals be ordered and work with animals be initiated. Designated member reviews are included as acknowledge items in the agenda and minutes of the next IACUC meeting.

If a proposal is disapproved, investigators are notified by memorandum listing the issues and concerns leading to the disapproval. They may respond by making revisions in their proposal and/or coming to a meeting of the IACUC to present their work or justifications. However, they are not allowed to order animals or initiate any animal activities.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing

activities as set forth in the PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Significant changes in previously approved activities involving the care and use of animals requires the development of an amendment or new proposal. Amendments to approved protocols are handled by Full Committee Review using the process described above in section 6.

The IACUC has allowed one exception to the Full Committee Review for some types of amendments. Amendments that are limited to changes (additions or deletions) of personnel other than the principal investigator or other changes minimal in nature may be reviewed using a designated member review (DMR) process. Examples of changes minimal in nature are minor alterations in a procedure, a dose of an agent that is already approved on other protocols under the same PI, small numbers of additional animals, or other minor issues. In this case, an amendment is prepared with the change described. The amendment is posted on our secure committee web site and an email is sent to all IACUC members requesting that the amendment be examined. The committee members have 48 hours to respond. If any IACUC member requests a full committee review of this amendment, that is done. If none of the members object, then the assigned designated reviewer performs the review. Assigned reviewers have the option of approving the amendment, requiring additional modifications, or sending it to full committee review. The investigator is informed of the action by memo and the results of the designated review are posted in the agenda and minutes of the next IACUC meeting. The IO is provided a copy of the minutes of all the IACUC meetings.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

Principal Investigators are notified of all actions regarding their IACUC submissions via memorandum. These memos are attached to emails sent to the investigator's preferred email addresses. The institutional official is notified of all IACUC activities and actions including those related to proposal and amendment reviews through receipt of copies of the IACUC meeting minutes. If the committee withholds approval, the investigator is notified in writing. The notification includes the reasons for withholding of approval and the investigator is allowed an opportunity to respond either in writing or in person. The IO is kept apprised of all IACUC actions on protocols by being provided copies of IACUC meeting minutes.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:

The IACUC Office requests a progress report at least annually from the investigator. These reports are reviewed at a convened meeting for acceptance. If the protocol has been active for three years, a new AUP is required for a de novo IACUC review prior to the expiration date of the protocol or work will halt until the de novo review has been completed and approved. Protocols undergoing triennial reviews are reviewed using full committee review procedures detailed in Part III.D.6.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

In order to suspend an activity, the IACUC must review the matter at a convened meeting with a quorum of the IACUC and the suspension must be approved by a majority vote of the committee. The Attending Veterinarian, in cases where the health, safety, or welfare of the animal is in jeopardy, has the authority to

"temporarily halt" the work until the IACUC can convene to review the situation and conduct official business. If the IACUC recommends suspension of an animal activity, then the IO in consultation with the IACUC reviews the reasons for suspension, takes appropriate corrective action, and reports the incident to OLAW.

E. The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows:

Institution's Occupational Health and Safety Program:

Scott & White Memorial Hospital have a professional services agreement for "Occupational Health and Safety Program Agreement for Animal Care and Use Facilities." This provides coverage for the Scott & White, Texas A&M Health Science Center, and Central Texas Veterans Health Care System staff and students working in animal laboratories on the Scott & White campus or on the Central Texas Veterans Health Care System campus. The Scott & White Clinic is a multi-specialty, medical practice group, with physicians in its employ whose responsibilities include preventative advice, and care of persons whose health exposures arise from their employment environment, and particularly include those physicians trained and experienced in the medical sub-specialty of Occupational Medicine.

The Scott & White IACUC is responsible for occupational health and safety issues for all personnel mentioned above. Investigators and their staff must read the *Occupational Health and Safety in the Care and Use of Research Animals Manual*. This manual includes hazard categories for bites and scratches, allergens, protocol related hazards, general safety; precautions, zoonoses, inherent hazards. Also included in the manual is information on the species they will be working with and explains recommended preventive measures, response to injury, and infectious diseases. Emergency contacts are included for various emergencies. A sheet is signed and sent to the Department of Occupational and Environmental Medicine Office acknowledging they have read and understand the material.

The PHS *National Institute for Occupational Safety and Health (NIOSH)* pamphlet explains how to prevent asthma in animal handlers. A sheet is signed and sent to the Department of Occupational and Environmental Medicine Office acknowledging they have read and understand the material.

The *Occupational Health Questionnaire* must be completed. According to the species they will be working with and the amount of exposure, the most current dates are completed on medical examinations, appropriate immunizations, etc. The Questionnaire also includes a health screening for pre-existing conditions. This form is reviewed by the Director of the Department of Occupational and Environmental Medicine. Additional information or medical treatments may be required prior to approval. The personnel can receive the requirements from doctors on the Scott & White campus.

The Department of Occupational and Environmental Medicine Office contacts the IACUC Office upon receipt of the three signed and approved forms; this information is entered into a database for the IACUC to review. Individual health forms and records are maintained in the Department of Occupational Medicine Office.

The Occupational Health Questionnaire and a Blood Borne Pathogens training course are required annually.

Hazards

The Scott & White IACUC uses the Animal Use Protocol (AUP) form from the investigator and a review by the Safety Officer to ascertain and identify hazards involved in each protocol. All such hazards are listed in the AUP, Section XII: Animal Experimentation Involving Hazards. The entire application, along with this page, is circulated to the appropriate Safety Officer/Committee for review and approval. The description may include use of biohazard agent (MSDS attached), laser use, radiation use, radioactive materials, recombinant DNA, and/or transport use. Amendments are

reviewed the same way. Approval must be received from the appropriate safety officials. Upon review, the safety officials may require a full-face mask (fitted by the Scott & White Employee Health) or other necessary precautions that may require written documentation from the investigator.

Hazardous Agents

During the review of a new application or amendments to a previously approved application, if an investigator requests to use a hazardous agent, a form is to be completed and the MSDS attached. Depending upon the request, various forms to complete are: the use of hazardous agents; laser use or radioisotopes; and radioactive materials. These forms include personal protective gear, safety precautions, and persons performing the procedures. The forms are approved by the official(s) according to the location of the procedure, dilution, and storage. Recombinant DNA is reviewed and approved by the Texas A&M University Institutional Biosafety Committee (IBC) for all TAMHSC laboratories. The Scott & White IBC reviews recombinant DNA and use of transgenic animals conducted in the Scott & White animal facilities and research laboratories.

Additional occupational and safety precautions:

- Specific issues related to exposure to animal allergens and to pregnancy with exposure to reproductive hazards are addressed individually with affected employees
- A new laboratory for an investigator must receive a site visit from the Attending Veterinarian to receive animals. The AV walks through the steps with the investigator on the route the animal takes to and from the holding area, where the animal will be placed in the laboratory, and reviews all safety precautions in and around the area.
- All outside entry doors into the laboratories or procedure rooms are identified with a sign. The sign will reflect animals in use when closed, biohazard room, caution "rat dander", protective clothing that must be worn to enter, etc. As appropriate.
- Signs are posted on freezers "for carcass use only", labels on containers in the laboratory, location of first-aid kit, and other signs for precautions and identification.
- MSDS for all agents in the laboratory must be complete and accessible to personnel.
- Each investigator is responsible for his/her staff to provide the required protective clothing training on occupation health and safety issues in their lab. Upon the investigator's request, training is accessible from several sources.

The Scott & White IACUC reviews these issues during the semiannual reviews when visiting each laboratory.

Bites, scratches and injuries related to animal use: A reporting mechanism and the description of the procedure are explained during protocol training course instructed by the Operations Manager prior to working with animals. Each principal investigator and laboratory is provided a pamphlet and package of forms that must be completed in event of bites, scratches, illnesses or injuries related to animal exposure. As new investigators plan to initiate animal activities, they are provided with these packets to review with their staff and for placement within their laboratories. When an injury occurs, treatment is provided and the events documented on the form. Forms are sent either from the Scott & White Employee Health Department, or the Scott & White emergency room which provides care for individuals on the campus working with animals. Annually, the IACUC requests reports from these departments of any injuries.

Description of Old World Monkey Safety Program

Animal Care personnel and research staff who enter the primate area of the vivarium are evaluated annually by Occupational Health for a negative TB status. When working with nonhuman primates, the date of MMR vaccination or measles antibody titer is documented by Occupational Health. Nonhuman primates are TB tested prior to transport to Scott & White. Nonhuman primates housed in Scott & White facilities are TB tested biannually. SPF macaques (negative for B virus) are purchased but B virus precautions remain in place at all times. Use of protective clothing is required when working with NHP's. This includes the use of double

gloving and eye protection with macaques in addition to other standard PPE. Any activity involving the generation of aerosols in macaque rooms (hosing cages and floors) requires the use of a PAPR. Nonhuman primates undergo an initial quarantine period (length of time determined by AV) and a series of TB test are conducted prior to release from quarantine by the AV. At this time macaques are housed in a hallway with limited research traffic.

Personnel with macaque contact are required to obtain B virus training through the Attending Veterinarian. This training is documented with the DCM and the IACUC. The training is conducted utilizing a PowerPoint presentation and a copy of the slides is provided to all that attend. The training covers the history of B virus exposure, explains what is considered an exposure, what steps to take in the event of an exposure, and how to avoid having an exposure occur. The Attending Veterinarian also provides training in working safely with macaques. Veterinarians and experienced DCM technicians train new staff working with new world monkeys.

Macaque exposure kits are located in refrigerators in close proximity to macaque housing and procedure areas. The SOP on macaque exposure is followed including immediate wound cleansing for 15 minutes and collection of viral samples from the macaque involved within 30 minutes. Bite wounds or scratches from new world primates are treated with first aid and staff are referred to the Scott and White Staff Health Department or Emergency department if appropriate.

All macaque exposures are documented and reported to the National B Virus Resource Center at Georgia State University and the Occupational health Director immediately. All staff with macaque exposures are referred to the Scott and White Staff Health Department or Emergency department (after hours) immediately following the initial 15 minute wound cleaning.

Additional Procedures in occupation health and safety issues

The Central Texas Veterans Health Care System (CTVHCS) performs inspections in the animal laboratories on the CTVHCS campus. Laboratories are inspected semi-annually by the facility staff and the VISN Industrial hygienist.

F. Appendix: The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Training or instruction in the humane practice of animal care and use is provided to all individuals who use or care for laboratory animals. The IACUC web site, (<http://medicine.tamhsc.edu/iacuc>., username: tamhsc.com, password: fqwhgads) provides the investigator and IACUC members with links of materials and resources and/or training. IACUC members are required to complete the AALAS Learning Library course on "Essentials for IACUC Members" before beginning to serve their term. Future members are also invited to attend an IACUC meeting to meet the committee and become familiar to the operation. The IACUC has a budget that allows members to attend IACUC 101 or SCAW IACUC training courses that are close to our location. The IACUC office includes handouts and web links in materials posted on our web site for members. We also obtain and provide copies of books or other materials related to animal care and use as resources for members.

Research technicians and scientists receive an initial tour of the facility and policies are explained such as "The Guide", the PHS Policy, and the "Animal Welfare Assurance". All are provided with a handbook of basic facility operation and attend a one hour training session. Prior to working with animals or having

independent access to the animal facility, all personnel must take the CITI course ("Working with the IACUC") and a Blood Borne Pathogens course and successfully pass the incorporated knowledge test. At both the initial tour and as the investigator applies for research projects using various species, specific training needs are identified and scheduled. Any of the Scott & White training courses offered to the animal facility technicians are also offered to the research technicians.

The search for alternatives and the results are included on the animal use protocol (AUP). IACUC reviews the results of that search, but also makes suggestions that might ease pain and stress, reduce the number of animals, or suggest medications or analgesics. Alternative databases are available on the website <http://medicine.tamhsc.edu/iacuc/>. The Scott & White library will also assist the investigator with the search. The attending veterinarian provides instruction in appropriate techniques for administering drugs, obtaining blood and tissue samples, and recognition of pain or distress in study animals.

Standard training initially begins when an investigator has an approved protocol. The investigator and all staff working with the animals are required to attend the protocol training class. Specialized training in the area the technician will be performing, is taught by the investigator, operations manager, or attending veterinarian. The names of all personnel working with animals are entered into a database that includes the date and type of training achieved and documentation is filed in a binder. Frequency depends on the type of training and refresher courses needed.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the "Guide." Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category One (1)—accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. RECORDKEEPING REQUIREMENTS

- A. This Institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto, as approved by the PHS.
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Richard Beswick, Ph.D. Records of accrediting body determinations.
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

- A. This Institution's reporting period is January 1 – December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The report will include:
1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide written notification that there are no changes.
 2. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Richard Beswick.
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy.
 2. Any serious deviations from the provisions of the "Guide."
 3. Any suspension of an activity by the IACUC.
- C. Reports filed under sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Richard Beswick, Ph.D.

Title: Director of Research


Name of Institution: Scott & White Memorial Hospital

Address: 2401 South 31st Street
Temple TX 76502
Medical Education Building Room 407G

Phone: (254)724-2368

Fax: (254)762-0301

E-mail: rbeswick@swmail.sw.org

Signature: 

Date: 8/20/10

B. PHS Approving Official

Name:

Title:

Address:

Phone:

Fax:

E-mail:

Signature:

Date:

C. Effective Date of Assurance:

D. Expiration Date of Assurance

MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

DATE: 04/09/2010
 NAME OF INSTITUTION: Scott & White Memorial Hospital
 ASSURANCE NUMBER: A3895-01

Chairperson Name, Title, and Degree/Credentials		Business Address, Phone, Fax, and Email of Chairperson
Name*: Thomas J. Kuehl		Address*: Scott & White Memorial Hospital 2401 South 31 st Street Temple, TX 76508
Title*: Chair, Scott & White IACUC; Professor; Depts of Ob/Gyn, Pathology, and Molecular and Cellular Medicine; Dir. Of Research, Dept of Ob/Gyn; Chief, Section of Andrology, Dept of Pathology		
Degree/Credentials*: Ph.D.	Phone*: (254) 724-2738	Fax*: (254) 724-7561
Email*: tkuehl@swmail.sw.org		

Name of Member/Code**	Degree/Credentials	Position Title	PHS Policy Requirements***
Kuehl, Thomas	Ph.D.	Chair	Scientist
Alpini, Gianfranco	Ph.D.	Professor, Director, Scott & White Digestive Diseases Research Center	Scientist
DeMorrow, Sharon	Ph.D.	Associate Professor/Research Scientist Cardiovascular/TAMHSC	Scientist
Gibson, Jane	M.A.	Professor of Spanish, Central Texas College, Creative Arts Minister, Belton Church of Christ	Nonaffiliated member
Gregory, Carl	Ph.D.	Assistant Professor Department of Molecular and Cellular Medicine Institute for Regenerative Medicine	Scientist
Lane, Jennifer	D.V.M.	Attending Veterinarian, Director Department of Comparative Medicine at Scott & White	Veterinarian
Pantusa, Victor	M.S.	TAMHSC HSC Chief Safety Officer	Nonscientist

Young, Keith	Ph.D.	Co-Director, Neuropsychiatry Research Program, CTVHCS Vice-Chair for Research, Dept. of Psychiatry, TAMHSC	Scientist
Zawieja, David	Ph.D.	Professor, Director of the Division of Lymphatic Biology, Department of Systems Biology and Translational Medicine	Scientist
Appointed Non-Voting Members			
Blackwood, Rebecca	D.V.M.	Sr. Veterinarian, Assoc Director, Comparative Medicine	Designated alternate for Dr. Jennifer Lane
Hitt, Angie	B.S., RLATG, CMAR	Assoc Director, Comparative Medicine – Operations	Ex Officio
Lindsey Harper	B.H.A.	CTVHCS Research Compliance Officer	Non-voting Member

*This information is mandatory.

**Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the Institution and available to authorized OLAW or other PHS representatives upon request.

***PHS Policy Requirements - identify which IACUC members meet the four criteria below:

- Veterinarian (V) - a veterinarian with direct or delegated program responsibility.
- Scientist (S) - a practicing scientist experienced in research involving animals.
- Nonscientist (NS) - a member whose primary concerns are in non-scientific areas (e.g. ethicist, lawyer, member of the clergy).
- Nonaffiliated (NA) - a member who is not affiliated with the Institution in any way other than as a member of the IACUC, and who is not a member of the immediate family of a person who is affiliated. This member is expected to represent the interests of the general community in the proper care and use of animals and should not be a laboratory animal user. A consulting attending veterinarian may not be considered nonaffiliated.

Notes:

1. All members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Ad hoc or nonvoting members may be listed and identified as such, but are not considered members for the purpose of the PHS Policy, and do not contribute to a quorum.
2. If Alternate members are listed, identify for whom (by name or code number, not specialty) they will serve as Alternates.

OTHER KEY CONTACTS (OPTIONAL)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Name:

Title:

Phone & Fax:

E-mail:

Name:

Title:

Phone & Fax:

E-mail:



Scott & White Institutional Animal Use and Care Committee

August 17, 2010

Office of Laboratory Animal Welfare/NIH
Division of Assurances
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982
(For express mail use ZIP 20817)

Enclosed, please find the revised Office of Laboratory Animal Welfare (OLAW) renewal application for Scott & White Memorial Hospital.

If we may be of any further assistance, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read 'Richard Beswick'.

Richard Beswick, Ph.D.
Director of Research
Institutional Official
Scott & White Memorial Hospital
2401 South 31st Street
Temple, Texas 76508

Phone: (254)724-2494
Fax: (254)724-7202
Email: rbeswick@swmail.sw.org

A handwritten signature in black ink, appearing to read 'Thomas J. Kuehl'.

Thomas J. Kuehl, Ph.D., Chair
Scott & White Memorial Hospital IACUC
Scott & White Memorial Hospital
2401 South 31st Street
Temple, Texas 76508

Phone: (254)724-2738
Fax: (254)724-7561
Email: tkuehl@swmail.sw.org

SAMPLE ANIMAL WELFARE ASSURANCE
In accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

This Animal Welfare Assurance (Assurance) sample document is provided to assist institutions with the development of an Assurance in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Reviewing the entire document and reading the PHS Policy before beginning to write will facilitate the completion of your institution's Assurance. Additional guidance, frequently asked questions (FAQs), and suggested references are available on the Office of Laboratory Animal Welfare (OLAW) website (<http://grants.nih.gov/grants/olaw/olaw.htm>).

This sample document should **not** be used by:

- Foreign institutions.
- Institutions that currently do not have their own animal care and use programs.
- Institutions that are proposing animal activity to be conducted solely at a collaborating institution.

If one of these bullets describes your institution, please contact OLAW by email at olawdoa@mail.nih.gov for guidance.

If you are unsure as to whether your institution is required to submit an Assurance and OLAW has not contacted your institution, please consult with OLAW. Do not submit an unsolicited Assurance. Assurances that have not been requested by OLAW will not be processed.

This sample document supersedes all previous versions. It includes all required elements of an Assurance. Words that are italicized and in brackets [*like this*] indicate specific information the institution must provide about its animal care and use program. Notes to help in preparation of the document are in brackets [NOTE: like this] and should be deleted from the completed Assurance. Please strive for clear concise text in the document. Adherence to the sample document format will facilitate the institution's preparation and OLAW's review of the Assurance.

One or two page attachments are preferred and may be used to provide the following:

- Organizational structure of the animal care and use program.
- Membership of the IACUC Roster.
- Facility and Species Inventory.
- Most recent semi-annual report of program and facilities. This is needed **only** for programs that are not Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) accredited.

All other program elements are to be described in the text of the Assurance. Please do not send additional attachments, more comprehensive attachments, or include appendices, binders, or manuals. Due to OLAW's use of electronic records, we will not accept these separate documents.

Submit completed Assurances to:
Office of Laboratory Animal Welfare/NIH
Division of Assurances
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982
(For express or hand-delivered mail use ZIP 20817)

All questions concerning this sample are to be directed to the staff of the Division of Assurances at 301-496-7163, or email OLAW at: olawdoa@mail.nih.gov

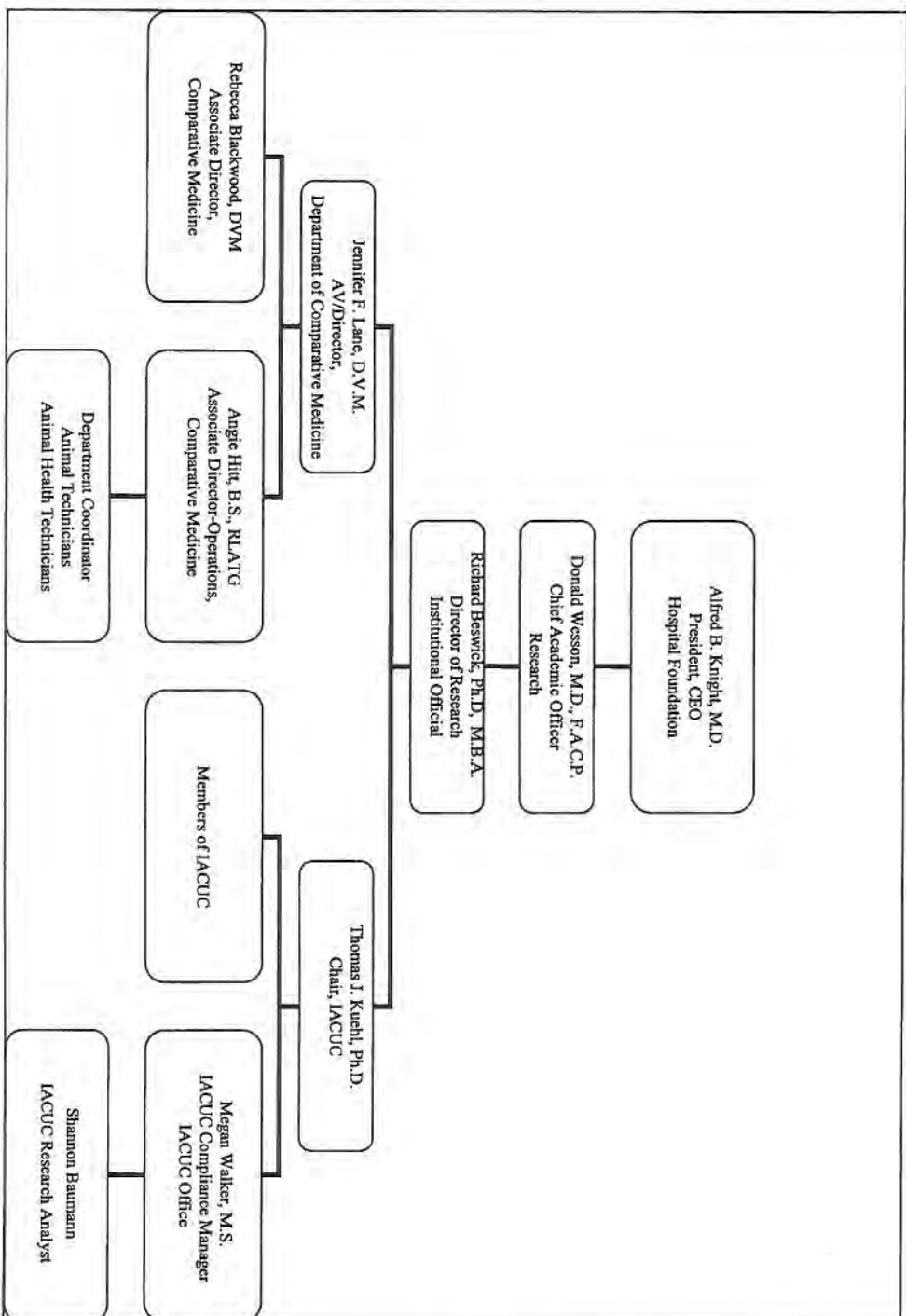
FACILITY AND SPECIES INVENTORY

DATE: 04/09/2010
 NAME OF INSTITUTION: Scott & White Memorial Hospital
 ASSURANCE NUMBER: A3895-01

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed in Unit (use complete common names)	Approx. Average Daily Inventory
Main vivarium (Building 25)	10,252	mice	1224
		rats	495
		rabbits	12
		squirrel monkeys	33
		Rhesus macaques	2
Building 25 Annex	640	pigs	6
Cancer Research Institute	1322	mice	28
		rats	50

*Institutions may identify animal areas in any manner, e.g., initials, ID number, etc. However, the name and location must be provided to OLAW upon request.

Scott & White Memorial Hospital Animal Care and Use Program Lines of Authority



Problem Resolution Process for Animal Care and Use Program

Scott & White expects all staff to use good judgment when making decisions regarding compliance issues for animal care and use. The NIH Guide and Scott & White Assurances provides broad direction for doing this. These guides do not cover every situation that arises in the workplace. For specific policies and procedures, employees should refer to the standard operating procedures and approved protocols.

If you believe that a violation of policy or law was committed, you are obligated to report it. Such issues should be raised to your immediate supervisor, the Chair of the IACUC, Attending Veterinarian or Chief Institutional Official.

- Chair of the Institutional Animal Care and Use Committee (IACUC)
Phone: 254-724-4533 or 254-743-2464

E-mail: ddostal@medicine.tamhsc.edu

- Attending Veterinarian
Phone: 254-724-5728 or 254-541-4086

E-mail: jlane@swmail.sw.org

- Chief Institutional Official for Scott & White
Phone: 254-724-2494

E-mail: rbeswick@swmail.sw.org

- Chief Institutional Official for Texas A&M Health Science Center
979-862-3315

E-mail: dcarlson@tamhsc.edu

If you believe the issue is not properly addressed, you must take your concern to the next level of management.

To encourage appropriate use of this reporting procedure, Scott & White has a non-retaliation policy that strictly prohibits any kind of retaliation or retribution against any employee who, in good faith, contacts their supervisor or institutional officials. All staff are treated with dignity and respect. Furthermore, caller anonymity and confidentiality will be maintained to the limits allowed by law.



Disciplinary Action

		Old Policy Number:	6.25
		New Policy Number:	X.5068.13.6.25
Manual Name:	Human Resources		
Scope(s):	Clinics Central Region	Hospital Continuing Care	
	Clinics College Station Region	Hospital Hillcrest Baptist	
	Clinics Hill Country Region	Hospital King's Daughters	
	Clinics Round Rock Region	Hospital Llano	
	Clinics Scott and White Region	Hospital Metroplex	
	Clinics Temple Memorial	Hospital Round Rock	
	Home Health	Hospital Santa Fe Skilled Nursing Facility	
	Home Infusion Services	Hospital Temple Memorial	
	Hospice		
Revisions:	Revision(s) to Policy		
Review Responsibility (Committee or Title):		Chief for Corporate Culture	
Approved:	01/2005		
Reviewed:	01/2005; 09/2009		
Revised:	09/2009		
KEYWORDS:	Disciplinary actions; counseling; suspected misbehavior; demotions; suspensions; terminations; human resources; hr; x.5068.13.6.25; 6.25;		

I. POLICY:

Management will conduct an investigation of suspected misbehavior on the part of employees to determine the circumstances surrounding the action. Executive Leadership and Human Resources will review the results of any investigation prior to initiating disciplinary action, if any.

Management is expected to reasonably monitor the actions of their employees and to conduct training and communications as necessary to maintain standards of conduct and performance. Management is also expected to take remedial action when necessary. The goal for most disciplinary actions should be corrective and involve progressive measures. Disciplinary measures should be applied consistently and in a non-discriminatory manner.

II. OPERATIONAL DEFINITIONS:

None

III. PROCEDURE:

- A. Human Resources must be consulted prior to disciplinary action that affects employment status (i.e. demotions, suspensions, and/or terminations). It is important to ensure documentation is adequate and correct, communications with the employee (and others) is appropriate to the case, and the actions recommended are consistent.

Human Resources / Disciplinary Action**Policy # X.5068.13.6.25**

- B. Management should document disciplinary or verbal counseling that may occur with employee. Originals of formal counseling documentation with appropriate signatures (Form #4103) should be sent to Human Resources for inclusion in the employees' employment method.
- C. If there is a suspicion that an employee has engaged in unacceptable behavior, Management should promptly conduct an investigation to determine the circumstances of the situation and the parties involved.
1. As soon as possible after the event, an interview should be conducted with the employee suspected of misconduct. The interview should be held in private, away from other employees. The employee should be given an opportunity to explain the incident and the circumstances surrounding it. This includes identification of witnesses the employee feels might have some knowledge of the facts. The interviewer should make detailed and accurate notes of interviews and other aspects of the investigation. If the employee is suspected of serious misconduct, Management may wish to consider suspending the employee during the course of the investigation (coordinated with Executive Leadership and Human Resources).
 2. Witness who might have knowledge of the facts surrounding the alleged incident should be interviewed. These interviews should take place as soon after the event in question as practical. The interviews should be conducted separately and in private. Detailed notes of these interviews should be kept. The interviewer may wish to take signed statements from the witnesses.
 3. If management feels significant disciplinary action is appropriate, the Human Resources Department should review the case with Management and Executive Leadership to determine the appropriate degree of discipline. The employee's employment record may be reviewed for other incidents and performance information. Executive Leadership and Human Resources should review and concur with any terminations, suspensions or disciplinary demotions before they are implemented to ensure they are defensible.
- D. The Human Resources Department is Scott & White's designated representative for dealing with outside agencies for labor relations' issue. As such communications with these agencies should be only through Human Resources. A copy of any communication from any such agency should be forwarded promptly to Human Resources for review.

Reference(s):

None

Related Forms or Web Link(s):

None

Related Plan(s):

None